

1 We claim:

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3 1. A method for the management of incontinence in a patient,
4 wherein the method comprises admitting orally into the patient a dosage form
5 comprising a member selected from the group consisting of oxybutynin and its
6 pharmaceutically acceptable salt, that is administered at a release rate of 0.05
7 mg per hour up to 0.850 mg per hour for the management of incontinence in
8 the patient.

9

10 2. The method for the management of incontinence in a patient
11 according to claim 1, wherein the dosage form is a sustained-release dosage
12 form and the pharmaceutically acceptable salt is a member selected from the
13 group consisting of acetate, bitartrate, citrate, edetate, chloride, edisylate,
14 estolate, esylate, fumarate, , gluceptate, gluconate, glutamate, bromide,
15 lactate, malate, maleate, mandelate, mesylate, methylnitrate, mucate,
16 napsylate, nitrate, pamoate, pantothenate, phosphate, salicylate, stearate,
17 succinate, sulfate, tannate, and tartrate.

18

19 3. The method for the management of incontinence in a patient
20 according to claim 1, wherein the dosage form is a controlled-release dosage
21 form and the oxybutynin is present as a racemate.

22

23 4. The method for the management of incontinence in a patient
24 according to claim 1, wherein the dosage form is a member selected from the
25 group consisting of a tablet, capsule, caplet, bead, and matrix and the
26 oxybutynin is present as the R-enantiomer.

27

28 5. The method for the management of incontinence in a patient
29 according to claim 1, wherein the dosage form is a member selected from the
30 group consisting of a tablet, capsule, caplet, bead and matrix and the
31 oxybutynin is present as the S-enantiomer.

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1 6. A method for treating incontinence in a patient exhibiting the
2 symptoms of incontinence, wherein the method comprises admitting orally
3 into the patient a sustained release dosage form comprising 240 ng to 650 mg
4 of a member selected from the group consisting of oxybutynin and its
5 pharmaceutically acceptable salt that is administered at a incontinence-
6 managing rate of 10 ng per hour to 20 mg per hour for the management of
7 incontinence.

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9 7. The method for treating incontinence in a patient according to
10 claim 6, wherein the method administers the pharmaceutically acceptable salt
11 oxybutynin chloride over 24 hours.

12
13 8. A method for the management of incontinence and for the
14 management of hormone replacement therapy in a patient, wherein the
15 method comprises administering a sustained-release therapeutically effective
16 dose of a member selected from the group consisting oxybutynin and its
17 pharmaceutically acceptable salt for the management of incontinence, and
18 administering a therapeutically effective dose of an estrogenic steroid for the
19 management of hormone replacement therapy to the patient in need of both
20 therapies.

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22 9. The method for the management of incontinence and for the
23 management of hormone replacement therapy according to claim 8, wherein
24 the oxybutynin and the estrogenic steroid are administered at the same time.

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26 10. The method for the management of incontinence and for the
27 management of hormone replacement therapy according to claim 8, wherein
28 a progestin is administered with the estrogenic steroid.

29
30 11. The method for the management of incontinence and for the
31 management of hormone replacement therapy according to claim 8, the
32 oxybutynin and the estrogenic steroid are administered at a different time.

1 12. The method for the management of incontinence and for the
2 management of hormone replacement therapy according to claim 8, wherein
3 the administration of the estrogenic steroid is accompanied by the
4 administration of a progestin steroid as a steroid pair and at a different time
5 from the administration of the oxybutynin.

6
7 13. The method for the management of incontinence and for
8 hormone replacement therapy according to claim 8, wherein the estrogenic
9 steroid is a conjugated equine estrogen.

10
11 14. A method for treating involuntary incontinence in a patient,
12 wherein the method comprises admitting orally into the patient a sustained
13 release once-a-day dosage form comprising 240 ng to 650 mg of a member
14 selected from the group consisting of oxybutynin and its pharmaceutically
15 acceptable salt, that is administered in a sustained rate to provide in the
16 plasma of the patient a higher oxybutynin/desethylmetabolite ratio then about
17 0.18 to 1 for treating involuntary incontinence in the patient.

18
19 15. A method for managing the concentrations of oxybutynin (OXY)
20 and its desethylmetabolite (DESOXY) in the plasma of a patient, and for
21 managing incontinence in the patient, wherein the method comprises
22 admitting orally into the patient a once-a-day dosage form comprising 240 ng
23 to 650 mg of a member selected from the group consisting of oxybutynin and
24 its pharmaceutically acceptable salt, that is administered at a controlled rate
25 to provide higher OXY/DESOXY ratio then about 0.18 to 1 for managing the
26 plasma concentrations and for managing incontinence in the patient.

27
28 16. A method for the management of overactive bladder and for
29 increasing compliance in a patient in need of said management and
30 compliance wherein the method comprises admitting orally into the patient a
31 once-a-day dosage form comprising 240 ng to 650 mg of a member selected
32 from the group consisting of oxybutynin and its pharmaceutically acceptable

1 salt that is administered in a sustained-release dosage of 0.10 ng per hour to
2 25 mg per hour for increasing patient compliance for the management of
3 overactive bladder in the patient.
4

5 17. The method according to claim 16, wherein the dosage form
6 comprises a polymer selected from the group consisting of an erodible,
7 nonerodible, diffusion, ion-exchange, and porous polymers.
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9 18. The method according to claim 16, wherein the dosage form is
10 an osmotic dosage form.
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12 19. The method according to claim 16, wherein the dosage form
13 comprises tiny pills.
14

15 20. The method according to claim 16, wherein the patient is
16 administered a member selected from the group consisting of an estrogen
17 and a progestin.
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19 21. The method according to claim 16, wherein the dosage form
20 comprises drug releasing beads.
21

22 22. A method for treating an overactive bladder in a female patient,
23 wherein the method comprises admitting orally into the patient a dosage form
24 comprising a member selected from the group consisting of oxybutynin and its
25 pharmaceutically acceptable salt that is administered in a controlled release
26 dose of 0.05 mg per hour to 0.850 mg per hour for treating the overactive
27 bladder in the female patient.
28

29 23. The method for treating the overactive bladder according to
30 claim 22, wherein the dosage form comprises a member selected from the
31 group consisting of poly(amide), poly(amino acid), poly(ester), poly(lactic

1 acid), poly(glycolic acid), poly(orthoester), poly(orthocarbonate), poly(acetyl),
2 poly(anhydride), poly(dehydropyran), poly(carbohydrate), and poly(dioxinone).

3
4 24. The method for treating the overactive bladder according to
5 claim 22, wherein the dosage form comprises a member selected from the
6 group consisting of an olefin, vinyl, condensation, addition, carbohydrate, and
7 silicon polymer.

8
9 25. The method for treating the overactive bladder according to
10 claim 22, wherein the dosage form comprises a member selected from the
11 group consisting of hydroxypropylalkylcellulose, and hydroxyalkylcellulose.

12
13 26. The method for the management of overactive bladder and
14 hormone replacement therapy in a female patient, wherein the method
15 comprises orally administering to the patient a member selected from a group
16 consisting of oxybutynin and its pharmaceutically acceptable salt at a
17 sustained release rate for the management of the overactive bladder, and
18 orally administering to the patient a composition comprising a steroid selected
19 from the group an estrogen and a progestin for hormone replacement therapy.

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21 27. The method for the management of overactive bladder and
22 hormone replacement therapy according to claim 26 wherein the oxybutynin
23 and the steroid are administered at the same time.

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25 28. The method for the management of overactive bladder and
26 hormone replacement therapy according to claim 26, wherein the oxybutynin
27 and the steroid are administered at different times.

28
29 29. The method for the management of overactive bladder and
30 hormone replacement therapy according to claim 26, wherein the estrogen is
31 a member selected from the group consisting of estradiol, estradiol valerate,
32 estradiol benzoate, estradiol cypionate, estradiol propionate, estradiol

1 dipropionate, estradiol acetate, ethinyl estradiol, 17 α -ethinyl estradiol, 17 α -
2 ethinyl estradiol esters, 17 α -ethinyl estradiol acetate, 17 α -ethinyl estradiol
3 benzoate, 17 α -ethinyl estradiol ethers, estrone, estrone acetate, estrone
4 sulfate, estriol, estriol succinate, estriol triacetate, conjugated equine
5 estrogens, and estradiol esters.

6
7 30. The method for the management of overactive bladder and
8 hormone replacement therapy according to claim 26, wherein the progestin is
9 a member selected from the group consisting of progesterone,
10 medroxyprogesterone, medroxyprogesterone acetate, hydroxyprogesterone,
11 hydrogesterone caproate, norethindrone, norethindrone acetate, megestrol,
12 megestrol acetate, progestin, progestogin, norgestrel, norethisterone,
13 norethisterone acetate, levonorgestrel, norgestimate, norethynodrel, 17-
14 hydroxyprogesterone esters, 19-nor-17-hydroxyprogesterone, 19-nor-17-
15 hydroxyprogesterone esters, 17 α -ethinyltestosterone, 17 α -ethinyl-19-nor-
16 testosterone, d-17 β -acetoxy-13 β -ethyl-17 α -ethinyl-17 β -hydroxygon-4-en-3-
17 one, 13 β -ethyl-17 β -hydroxygon-4-en-3-one, 13 β -17 α -diethyl-17 β -hydroxygon-
18 4-en-3-one, chlormadione acetate, dimethistrone, 17 α -ethinyl- β -acetoxy-19-
19 norandrost-4-en-3-one oxime, 3-ketodesogestrel, desogestrel, gestodine, and
20 gestodene acetate.

21
22 31. The method for the management of overactive bladder and
23 hormone replacement therapy according to claim 26, wherein the oxybutynin
24 is administered from a dosage form selected from the group consisting of
25 osmotic, diffusion, erodible, nonerodible, and ion-exchange dosage forms.